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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,772

Applicant(s)

FEUSSNER ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/1/04, 2/03/05, 5/24/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 15-18, 20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendment filed February 3, 2005 and May 24, 2005; and the response filed November 1, 2004 have been entered.

Claims 1 and 4-14 are currently amended, since the first office action of July 29, 2004.

Claims 1-18, 20 and 22 are pending

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains claims 2, 3, 15-18, 20 and 22 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1 and 4-14 are examined on the merits.

Specification

The substitute specification has been received and entered.

The specification is still objected to for failure to comply with the sequence rules which require that all sequences be identified by a SEQ ID number. The sequences provided in Figure 2 are not identified by SEQ ID number either in the figure or in the specification. Correction is required. A new CRF, a new paper copy of the sequence listing, and a letter stating that the CRF and the paper copy are the same, are each required.

Applicants' arguments filed February 3, 2005 have been fully considered but they are not persuasive. Applicants assert that SEQ ID NO: 2 is the first sequence of Figure 2 and is identified at pages 34-35 of the substitute specification. However, the Examiner cannot find a recitation of SEQ ID NO: 2 on those pages. In addition, Applicants argue that all of the other sequences are in the public domain. However, the Examiner maintains that to comply with the sequence rules, all sequences set forth in the specification must be identified by SEQ ID NO. This includes all of the primer sequences on pages 34-35, the sequences set forth in Figure 2 and any other sequences provided in the specification or drawings.

Claim Rejections - 35 USC § 112

1. Claims 8, 9, 11 and 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 11 and 12 remain rejected given that it is unclear what is intended by "functional" and "nonfunctional", since no particular function is specified.

2. Applicant's arguments filed November 1, 2004 have been fully considered but they are not persuasive. Applicants assert that the amendment of the claims overcomes the rejection. However, the Examiner maintains that it remains unclear what is intended, as stated above.

Claim 11 remains indefinite in the recitation of "oil-producing" organism, given that the Examiner is unaware of any organisms that do not produce some form of oil. Therefore, it is unclear what is intended.

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Applicant's arguments filed November 1, 2004, February 3, 2005 and May 24, 2005 have been fully considered but they are not persuasive. Applicants assert that claim 9 has been amended to clarify this term. The Examiner maintains that this term is still used in claim 11, which does not depend from claim 9.

Claim 9 is indefinite in the recitation of "an organism capable of synthesizing fatty acids", given that the Examiner is unaware of any organisms that do not produce fatty acids, and the definition provided in the specification at pages 19-20 is open-ended. Therefore, the metes and bounds of the claimed invention are not clearly set forth.

All of the other rejections under 35 U.S.C. 112, second paragraph have been withdrawn in view of Applicants amendment of the claims.

Claims 1 and 4-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last office action.

Applicants' arguments filed November 1, 2004 have been fully considered but they are not persuasive. Applicants' assert that the expression of the gene and analysis of the lipids are presented in Examples 4 and 5 such that other sequences could be tested for their enzymatic activity without undue experimentation and would be able to practice the invention.

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The Examiner maintains that the desaturase of SEQ ID NO: 2 is not sufficient to define the genus, which includes desaturases having as little as 10% of the activity of the polypeptide of SEQ ID NO: 2, and arguments based on undue experimentation are not relevant to the written description rejection.

3. Claims 1 and 4-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding the calendulic acid desaturase of SEQ ID NO: 2, and expression of said enzyme in yeast, does not reasonably provide enablement for any desaturase coding sequence that codes for a protein having at least 75% homology to SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons set forth in the last office action, and repeated.

Applicants' arguments filed November 1, 2004 have been fully considered but they are not persuasive. Applicants' assert that the expression of the gene and analysis of the lipids are presented in Examples 4 and 5 such that other sequences could be tested for their enzymatic activity without undue experimentation and would be able to practice the invention.

The Examiner maintains that the specification has only provided one working example comprising the nucleic acid of SEQ ID NO: 2 transformed into yeast. For all of the reasons set forth in the last office action, it would require undue experimentation for one skilled in the art to make and/or use the invention, as broadly claimed.

Claim Rejections - 35 USC § 102

4. Claims 1 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hitz (US Patent 5,846,784), as stated in the last office action.

5. Applicants' arguments filed November 1, 2004 have been fully considered but they are not persuasive. Applicants' assert that Hitz (WO 98/56922) teaches a delta-12-fatty acid epoxygenase, and not a desaturase. The Examiner maintains that the rejection is over Hitz (US Patent 5,846,784), not to Hitz (WO 98/56922), so the argument is not persuasive.

Claim Rejections - 35 USC § 103

6. Claims 1 and 4-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBonte et al (US Patent 5,850,026), and further in view of Hitz (US Patent 5,846,784), as stated in the last office action.

Applicants' arguments filed November 1, 2004 have been fully considered but they are not persuasive.

7. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., introducing a double bond into a fatty acid molecule which already has two double bonds) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

8. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, Applicants' assert that Hitz (WO 98/56922) teaches a delta-12-fatty acid epoxxygenase, and not a desaturase. The Examiner maintains that the rejection is over DeBonte in combination with Hitz (US Patent 5,846,784), not to Hitz (WO 98/56922), so the argument is also not persuasive for this reason.

Conclusion

Claim 13 is deemed free of the prior art given that increasing calendulic acid in an organism transformed with a desaturase coding sequence was not known or suggested in the prior art of record.

No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

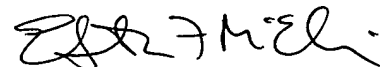
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Elizabeth F. McElwain, Ph.D.
Primary Examiner
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EFM